REMARKS/ARGUMENTS

Applicants acknowledge with appreciation the allowance of claims 26 and 27. In reviewing the claims, however, an error in the automatic claim numbering has been noted. An additional claim at [c9] was not recognized by the EFS software. Consequently, the claims after [c9] have been correctly numbered above. The claim now numbered 10 is a dependant claim dependant on claim 7, and is not believed to affect the examiner's analysis. The dependant claim references to preceding claims were correct as originally filed. The allowed claims are, therefore, now correctly numbered 27 and 28. Applicants paid the fee for 28 claims, so no additional fee is due for the uncounted claim.

With respect to claims 1-26 (as correctly numbered), the examiner has raised the issue of non-statutory double patenting. Because these claims have been presented in response to a restriction requirement imposed in the parent case, applicants respectfully traverse this ground of rejection and request the allowance of the claims.

This case is a divisional filed from US application 09/803,304, now US Patent 6,730,055. The claims originally filed in the parent case were made subject to a restriction requirement, dividing the claims into three groups. Applicants traversed the requirement on the grounds that the grouped claims were not related as combination and sub-combination. The examiner found this traversal persuasive, but maintained the restriction requirement on the grounds that the groups were unrelated inventions. (See Office Action of 8/5/2003.) The examiner explained the grounds for the restriction as follows:

"The invention in Group I [Claims 1-27], drawn to a method, does not require removal of return of fluid to the patient. Group II's [Claims 28-39] method and device requires removal of fluid from the patient, processing the fluid, and returning the unused portions to the patient. It does not require selection of a donor characteristic."

The examiner's comments with respect to Group III, Claims 40-61, are omitted herein, as the claims of Group III are not pursued in this divisional application. The claims of this application are derived from Group II. Having been made subject to a restriction requirement, these claims should not now be rejected for double patenting. Claims 1-26 of this application retain the limitations identified by the examiner as distinguishing Group II from Group I, the claims prosecuted and allowed in the parent case. This is clear from claim 1, the independent claim from which claims 2-26 depend:

> **Claim 1** (Previously presented) A method for extracorporeal collection of blood components from a donor/patient comprising:
> **removing blood from a donor/patient through a single needle;**
> flowing said blood into a dual stage blood processing vessel;
> separating plasma from said blood within said blood processing vessel;
> collecting at least a portion of said plasma in a plasma collection reservoir separate from said blood processing vessel;
> separating red blood cells from said blood within said dual stage blood processing vessel;
> collecting at least a portion of said separated red blood cells in a red blood cell collection reservoir separate from said blood processing vessel, wherein said plasma separation and collection steps are completed at least partially contemporaneously with said red blood cell separation and collection steps;
> **returning uncollected blood components of said blood to said donor/patient through said single needle; and**
> **replacing fluid volume in said donor/patient by flowing a replacement fluid to said donor/patient through said single needle**.

[Emphasis added.] A comparison of this claim to claim 1 of the '055 patent shows that, as noted by the examiner, the claim of the '055 patent does not require removal or return of fluid with the patient:

> Claim1 (Allowed in US 6,730,055) A method for extracorporeal separation and collection of blood components from a donor/patient, comprising:
> flowing blood into a centrifugal dual stage blood processing vessel, said processing vessel including a first stage and a second stage, the second stage being separated from said first stage by a dam, a blood inlet for communicating blood into the first stage, a plasma outlet disposed in the second stage and a red blood cell outlet disposed in the first stage;
> centrifugally separating the blood into separated blood components including;

separating plasma from said blood within said centrifugal dual stage blood processing vessel to establish separated plasma, whereby a portion of the separated plasma flows over the dam in the processing vessel to the plasma outlet in the second stage of the processing vessel;

separating red blood cells from said blood within said centrifugal dual stage blood processing vessel to establish separated red blood cells whereby the separated red blood cells remain in the first stage of the processing vessel and flow to the red blood cell outlet;

establishing a pre-determined packing factor for the separated red blood cells within said blood processing vessel;

collecting at least a portion of at least one separated blood component including;

collecting as a double red blood cell product at least a portion of said separated red blood cells in a red blood cell collection reservoir separate from said blood processing vessel to establish collected red blood cells.

In the words of the examiner ". . . the inventions are independent, since they have different modes of operation and different results." [Office action of 8/5/2003.]

"If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall be entitled to the benefit of the filing date of the original application. A patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the divisional application is filed before the issuance of the patent on the other application." [35 USC 121. Emphasis added. See also MPEP 804.]

"Where an applicant files a divisional application claiming a species previously claimed but nonelected in the parent case, pursuant to and consonant with a requirement to restrict, there should be no determination of whether or not the species claimed in the divisional application is patentable over the species retained in the parent case since such a determination was made before the requirement to restrict was made.

In a national application containing claims directed to more than a reasonable number of species, the examiner should not require restriction to a reasonable number of species unless he or she is satisfied that he or she would be prepared to allow claims to each of the claimed species over

the parent case, if presented in a divisional application filed according to the requirement. Restriction should not be required if the species claimed are considered clearly unpatentable over each other." [MPEP 806.04(h). Emphasis added.]

This divisional case is filed pursuant to a restriction requirement and the distinctions identified by the examiner as distinguishing between the two species of patentably distinct inventions have been maintained in the claims. It is respectfully suggested that the examiner's previous determination of patentable distinctiveness between the two sets of claims is binding. The rejection based on the parent case US 6,730,055 should be withdrawn.

Applicants, therefore, respectfully request the examiner's reconsideration and allowance of the case. If any matters remain to be resolved, the undersigned attorney respectfully requests that the examiner call him.

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Dated

Respectfully submitted,

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